

Washington D.C. 20505

16 June 1980

Ms. Barbara Mishkin
Acting Director
President's Commission for the Study
of Ethical Problems in Medicine and
Biomedical and Behavioral Research
2000 K Street, N.W.
Washington, D.C. 20006

Dear Ms. Mishkin:

This communication will serve as a reply to your letter of 6 March 1980 and as a sequel to the preliminary letter of response of 25 April 1980 concerning your questions as to biomedical or behavioral research involving human subjects which are conducted or supported under Central Intelligence Agency auspices. The Central Intelligence Agency does support or sponsor research in the biomedical and behavioral sciences. All research is conducted in accordance with Department of Health and Human Services (DHHS) guidelines -- formerly Department of Health, Education and Welfare guidelines.

In further response, we provide additional information. Current research activities involve: (a) the development of noninvasive procedures for analysis of physiological functions; (b) the development of microanalytic techniques for forensic analysis; (c) the study of cognitive function with emphasis on language processing; (d) the study of personality types and associated physiological responsivity; (e) the study of biofeedback principles and techniques; (f) the development of procedures for automated speech processing; (g) the study of stage make-up techniques. Excluded are those activities which are intended for administrative or operational data gathering analysis only.

All research with human subjects supported or sponsored by the Central Intelligence Agency is conducted under provisions of the Executive Order 12036, entitled "United States Intelligence Activities," dated 24 January 1978. Section 2, part 3, item 302, entitled "Restrictions on Experimentation," is attached for your reference (Enclosure A). The language of the Executive Order has been incorporated in the internal operating regulations of the Central Intelligence Agency. Regulation is attached for your review (Enclosure B). At this time,

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research with human subjects is conducted solely by external institutions under contract to the Central Intelligence Agency. Solicitations of research proposals involving work with human subjects, and all contracts for the conduct of such work, carry language implementing both the Executive Order and internal operating regulations. The applicable section of a current contract is attached for your examination (Enclosure C). Thus, the Executive Order, internal Agency regulations, and formal contractual practices require adherence to DHHS regulations as amended in 43 Federal Register 51559, 3 November 1978.

Enclosure C, noted above, conveys the general requirements for initial and ongoing review of human subject research practices. In addition, Central Intelligence Agency research program managers provide continuing review through site visits which are held at least annually with each contractor. Neither injuries nor departures from approved protocols have been reported or discovered since adoption of the DHHS guidelines as the minimum acceptable standards governing human subject research supported or conducted by the Central Intelligence Agency.

We wish to note, in passing, that the excerpt provided to the Agency in your 6 March 1980 communication, and taken from the report of the National Commission, refers to the Intelligence Community and efforts by the Intelligence Community Staff to draft a Community-wide directive. This draft directive was based in part on Central Intelligence Agency guidelines extant at the time. These guidelines entitled, "Guidelines for Human Subject Research," and signed by the Deputy Director of Central Intelligence on 26 March 1977, were applied Agency-wide. They were enforced prior to the preparation of the draft Community-wide directive which you provided to us, and they required adherence to the DHHS guidelines in all human research and not just narrowly to drug experimentation. However, the Central Intelligence Agency is but one member of the Intelligence Community. Our reply is for it alone. We assume that you are also making similar inquiry into the practices of other members of the Community.

The Central Intelligence Agency particularly supports the two proposals detailed in 44 Federal Register 47688 (14 August 1979) listed as (4) exempt from coverage certain kinds of social, economic and educational research and (5) exempt or require expedited review of certain kinds of research involving solely the use of survey instruments, solely the observation of public behavior, solely the study of documents, records or specimens or solely a combination of any of these activities. This response of the Central Intelligence Agency has excluded those activities which are actually administrative or operational data-gathering and analyses only.

The Central Intelligence Agency has not previously taken action or commented with respect to the proposed modifications enumerated above.

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In conclusion, the Central Intelligence Agency wishes to assure you of the desire to be responsive and cooperative with you in carrying out the mandate of the Commission. Please feel free to call [redacted] Central Intelligence Agency liaison with the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, [redacted] for further information or if he may be of further assistance.

Sincerely,

[redacted]

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Frank C. Carlucci
Acting Director

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